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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,884	03/12/2004	Viswanathan Srinivasan	P24615	4898

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
12/22/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/798,884	SRINIVASAN ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *117-200* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *117-200* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 11/08/11 are acknowledged.

2. Claims 118 and 191 were amended.

3. Claims 117-200 are included in the prosecution.

Response to Arguments

Claim Objection

4. In light of the amendment of claim 191 to correct the dependency, the objection with respect to this claim is withdrawn.

MAINTAINED REJECTIONS:

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 117-119, 134-139, 166, 167, and 175-179 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502).

The claimed invention is a pharmaceutical dosage form which comprises (a) a first drug which comprises at least one morphine derivative having antitussive activity and (b) at least one second drug, wherein a plasma half-life of the at least one second drug differs from a plasma half-life of the first drug and wherein the dosage form provides a plasma concentration within a therapeutic range of the at least one second

drug over a period which is coextensive with at least about 70% of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug.

Fanara teaches a pharmaceutical composition (including a multi-layered pharmaceutical composition) for oral administration that allows the release of at least one active substance and includes a matrix (Abstract). Fanara teaches: "The release of active substances during oral administration can be controlled by means of matrix-type pharmaceutical compositions" (Col. 1, lines 14-16). The compositions "can be administered in a few daily doses, ideally in a single daily dose" (Col. 1, lines 9-13). Fanara further teaches that: "… it is increasingly advantageous to be able to simultaneously administer by oral route an active substance released immediately after administration, and the same or a second active substance released gradually and regularly after administration … this makes it possible to obtain combined therapeutic effects by means of two active substances having very different pharmacokinetic profiles" (Col. 2, lines 36-50).

Since the same or a second active substance are disclosed in the pharmaceutical compositions (Col. 2, lines 36-50), it is obvious that the therapeutic effect from the controlled release of the actives would be the result of the administration of the pharmaceutical composition.

A person of ordinary skill in the art can interpret the 70% coextensive therapeutic range of the at least second drug as being 70% **within** the therapeutic range of the first

drug or that there is 70% **overlap** between the therapeutic ranges of the first drug and the at least second drug.

This reference also teaches that the "controlled-release pharmaceutical compositions can be used in combination with an immediate-release pharmaceutical composition for the same or for another active substance, in a single unit intended to be administered orally" (Col. 3, lines 32-37). This renders obvious the simultaneous or coextensive therapeutic range of more than one active drug in a single dosage form, as instantly claimed.

Fanara teaches that antihistamines, antitussives, such as codeine, morphine, and their pharmaceutically acceptable salts, along with pseudoephedrine, and phenylepherine may be included in the composition (Col. 4, lines 54-67). The pharmaceutical composition can be in the form of tablets (Col. 5, lines 18-20). The tablets can be bilayered (Col. 5, lines 48-58) or multilayered (Col. 6, lines 20-26). Example 7 of this reference discloses a double-layer tablet (with the two layers stuck to each other) containing 15mg doses of hydrocodone bitartrate (10mg of the hydrocodone is in a controlled release layer and 5mg of the hydrocodone is in an immediate release layer (Col. 12, line 25-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pharmaceutical composition having combined therapeutic effects of more than one active substance, as suggested by Fanara, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the pharmaceutical composition as taught by Fanara allows the release of the "active substances such that a satisfactory therapeutic effect is observed over fairly long periods, for example in only one or even two daily doses" (Col. 3, lines 22-27).

The pharmaceutical dosage form comprising a first drug (morphine derivative having antitussive activity) and a second drug where the dosage form provides a plasma concentration within a therapeutic range of the second drug over a period which is coextensive with at least about 70% of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug would have been obvious to one of ordinary skill in the art over Fanara. As mentioned above, Fanara teaches simultaneously administering more than one active substance and combining the therapeutic effects of active substances with different pharmacokinetic profiles (Col. 2, lines 36-50) and includes antitussives, antihistamines, codeine, and morphine as possible active substances in the composition. In order to have the combined therapeutic effects of active substances, it would have been obvious to one with ordinary skill in the art that the period of therapeutic effectiveness of the first active substance would be coextensive with the period of therapeutic effectiveness of the second active substance, especially if the two active substances are related to similar (antitussive) therapeutic activities.

The elected species of a bilayered tablet would have been obvious to a person with ordinary skill in the art over the Fanara teaching of bilayered tablets and matrix.

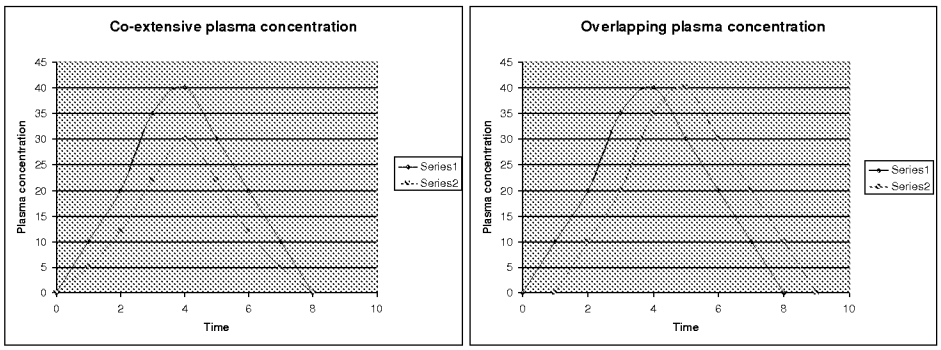
Response to Arguments

7. Applicants' arguments, see Pages 22-25, filed 11/08/11, with respect to the rejection of claims 117-119, 134-139, 166, 167, and 175-179 under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502) have been fully considered but are not persuasive.

Applicants traverse the rejection for all of the reasons which are set forth in the Appeal Brief filed October 20, 2008 and the Reply Brief filed August 25, 2009. Applicants argue that based on the reliance on Col. 2, lines 36-50 of the Fanara reference, "The Examiner still appears to take the position that in view of the above passage one of ordinary skill in the art allegedly would have an apparent reason to provide a dosage form which comprises two different active substances (having different half-lives), one released immediately after administration and the other one released gradually and regularly after administration, and releases the two active substances in such a manner that the plasma concentration of one active substance is within a therapeutic range over a period which is coextensive with at least about 70 % of the period over which the plasma concentration of the other active substance is within a therapeutic range." Applicants argue that Fanara does not explain what exactly is to be understood by the phrase "very different pharmacokinetic profiles" and that the term "pharmacokinetic profile" encompasses a wide range of properties of a drug. . Applicants submitted a definition of the term "pharmacokinetic profile" according to http://www.nature.com/nrg/journal/v4/n10/glossary/nrg1180_glossary.html (of record).

This is not persuasive because, as discussed in the Examiner's Answer (mailed 06/25/2009) the interpretation of claim 117 regarding the limitation "the dosage form provides a plasma concentration within a therapeutic range of the at least one second drug over a period which is coextensive with at least about 70% of a period over which the dosage form provides a plasma concentration within a therapeutic range of the first drug" can be as follows:

A or B



As the hypothetical figures above indicate, a person of ordinary skill in the art can interpret the 70% coextensive therapeutic range of the at least second drug as being 70% within the therapeutic range of the first drug (as in scenario A). The interpretation according to Scenario B is that there is 70% overlap between the therapeutic ranges of the first drug and the at least second drug.

Applicants argue that it is only with hindsight that one can conclude that the above passage of Fanara renders it obvious to one of ordinary skill in the art to use an immediate/controlled release combination for providing plasma concentrations in a therapeutic range of two active substances (whose half-lives are different) in a way such

that the therapeutically effective period of one drug overlaps at least about 70 % of the therapeutically effective period of the other drug.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants argue that there is not even a single passage in Fanara wherein the duration of action of any active substance relative to the duration of action of another active substance that is present in the same dosage form is addressed, and that whenever combinations of active substances are mentioned in Fanara these combinations are to be contained in immediate release/controlled release dosage forms.

This is not persuasive because the teaching of the reference is not limited to the exemplified embodiments. Fanara teaches that “controlled-release pharmaceutical compositions can be used in combination with an immediate-release pharmaceutical composition for the same or for another active substance, in a single unit intended to be administered orally” (Col. 3, lines 32-37). This renders obvious the simultaneous or

coextensive therapeutic range of more than one active drug in a single dosage form, as instantly claimed.

Since Fanara teaches a composition "where an active substance is released immediately and another active substance is released gradually, this makes it possible to obtain combined therapeutic effects by means of two active substances having very different pharmacokinetic profiles" (Col. 2, lines 46-50). It would be obvious to one of ordinary skill in the art that with the varying release profiles of the different actives, the "combined therapeutic effects" would only be accomplished if the plasma concentrations of the actives were within or "substantially coextensive" with the therapeutically effective range of the two actives.

Applicants further note that the Examiner apparently was unable to cite any document which in combination with Fanara could be considered to render it obvious to one of ordinary skill in the art to use the immediate/controlled release dosage forms set forth in Fanara for providing a plasma concentration within a therapeutic range of one drug over a period which is coextensive with at least about 70 % of the period over which the plasma concentration of any other drug (and specifically, a morphine derivative having antitussive activity) is in the therapeutic range, let alone in a situation where the half-lives of the drugs are different.

This is not persuasive because Fanara teaches antihistamines, antitussives, such as codeine, morphine, and their pharmaceutically acceptable salts, along with pseudoephedrine, and phenylepherine (Col. 4, lines 54-67). The limitation of the

coextensive therapeutic ranges is discussed above. Therefore, the rejection of 07/08/11 is maintained.

Claim Rejections - 35 USC § 103

8. Claims 120-123, 128-133, 140-153, 155-157, 159-165, 168-174, 180-195, and 198-200 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502) in view of Jaeger (US 3,914,425).

The teaching of Fanara is stated above.

Fanara does not expressly teach codeine phosphate as the active substance.

Jaeger teaches an antitussive codeine composition. Example 2 of this reference illustrates a three-layer "pill" or tablet containing codeine phosphate (Col. 2, lines 43-47). "An intermediate layer containing 6mg each of the two active ingredients was protected by a thin coating … and the outer layer contained 18mg codeine phosphate". Jaeger also teaches "preparations containing codeine may additionally contain antihistamines such as triprolidine hydrochloride, decongestants such as pseudoephedrine hydrochloride, and expectorants such as glyceryl guaiacolate" (Col. 3, lines 3-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pharmaceutical composition having combined therapeutic effects of more than one active substance, as suggested by Fanara, in view of the codeine phosphate and second active substances (antihistamines, decongestants, and expectorants) as suggested by Jaeger and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the pharmaceutical composition as taught by Fanara allows the release of the "active substances such that a satisfactory therapeutic effect is observed over fairly long periods, for example in only one or even two daily doses" (Col. 3, lines 22-27). The second drugs taught by Jaeger would have been obvious to one of ordinary in the art as supplementing the antitussive first drugs for ameliorating cough symptoms.

Regarding instant claims 128-130, one with ordinary skill in the art would use the teachings of Fanara and Jaeger to make a pharmaceutical composition by using drug combinations (antitussives, antihistamines, decongestants, expectorants) with drugs having different plasma half-lives in order to optimize the release of drugs over time. Drugs that are part of the immediate release would have a different plasma half-life than drugs that are part of the controlled release in order to maintain drug release for optimal therapeutic effect.

Regarding instant claims 131-133,145-146, 159, and 161, one with ordinary skill in the art would use the teachings of Fanara and Jaeger to make pharmaceutical compositions using drugs with different pharmacokinetic profiles (Fanara, Col. 2, lines 46-50). The claim limitations of periods of plasma concentration within the therapeutic range of the second drug being coextensive with at least about 80%, 90% or 95% of periods of plasma concentration within the therapeutic range of the first drug would have been obvious over the different pharmacokinetic profiles taught by Fanara in view of the antitussive codeine composition taught by Jaeger.

9. Claims 124-127, 154, 158, and 196-197 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502) in view of Jaeger (US 3,914,425) and further in view of Findlay et al. (US 4,650,807).

The teachings of Fanara and Jaeger are stated above.

Fanara and Jaeger do not expressly teach chlorpheniramine, promethazine, and guaifenesin.

Findlay teaches antihistaminic compositions. These compositions include tablets (Col. 5, lines 33-35). Antihistamines such as pheniramines, and promethazine are disclosed (Col. 1, lines 26-28). It is also taught that, "the active compound may be formulated with a sympathomimetic agent such as decongestants pseudoephedrine or phenylpropanolamine, an antitussive such as codeine … or an expectorant such as guaifenesin" (Col. 5, lines 9-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pharmaceutical composition with combined therapeutic effects of more than one active substance, as suggested by Fanara, in view of the codeine phosphate and second active substances (antihistamines, decongestants, and expectorants) as suggested by Jaeger and further in view of the specific antihistamines and expectorant as suggested by Findlay and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the specific active substances taught by Findlay supplement the antitussive first drugs for ameliorating cough symptoms.

Response to Arguments

10. Applicants' arguments, see Pages 25-27, filed 11/08/11, with respect to the rejection of claims 120-123, 128-133, 140-153, 155-157, 159-165, 168-174, 180-195, and 198-200 under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502) in view of Jaeger (US 3,914,425) and the rejection of claims 124-127, 154, 158, and 196-197 under 35 U.S.C. 103(a) as being unpatentable over Fanara et al. (US 6,699,502) in view of Jaeger (US 3,914,425) and further in view of Findlay et al. (US 4,650,807) have been fully considered but are not persuasive.

Applicants argue that it is not seen that the disclosure of Jaeger in combination with that of Fanara renders it obvious to provide the subject matter of any of the rejected claims, and neither has the Examiner provided any explanation in this regard.

This is not persuasive because the limitation of the coextensive therapeutic range of two different active drugs in a single dosage form is addressed in the rejection over Fanara. Jaeger is used to cure the deficiency of codeine phosphate as the active substance. Since the primary reference, Fanara, teaches that more than one active substance can be used in a single dosage form with coextensive or overlapping therapeutic ranges, and Jaeger provides the teaching of an antitussive codeine composition, one of ordinary skill in the art would find it obvious to combine the two references. The motivation to combine Fanara with Jaeger is provided by the fact that both references are useful for the same purpose (i.e. antitussive). It would have been obvious to combine equivalents that are known for the same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Applicants argue that the Examiner has not provided any documentary or other evidence to support the merely conclusory statements (in the paragraph bridging pages 7 and 8 of the Office Action mailed 07/08/11). Applicants argue that neither Fanara nor Jaeger even mention differences in half-lives of two drugs, let alone teach or suggest that two drugs whose half-lives differ significantly (e.g., by at least about 2 hours) should be combined in a way such that their periods of therapeutic effectiveness are substantially coextensive.

This is not persuasive because Fanara teaches that it is possible to obtain combined therapeutic effects by means of two active substances having very different pharmacokinetic profiles (Col. 2, lines 36-50). One of ordinary skill in the art would find it obvious that by choosing two different active substances, the plasma half-life of each drug can be determined during the process of routine experimentation. The limitation of the difference in plasma half-lives of two drugs would have been obvious given the drugs with different pharmacokinetic profiles and the determination of the plasma half-lives.

Applicants argue that Findlay appears to have been cited by the Examiner merely in order to show that it is known in the art that (certain) antihistamines may be formulated together with decongestants, antitussives and the like. Applicants argue that this is clearly not a reason for one of ordinary skill in the art to provide the subject matter of any of the present independent claims, either.

This is not persuasive because obviousness based on Fanara, and the combination of Fanara and Jaeger is discussed in detail above. Findlay is used to cure

the deficiency of chlorpheniramine, promethazine and guaifenesin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pharmaceutical composition with combined therapeutic effects of more than one active substance, as suggested by Fanara, in view of the codeine phosphate and second active substances (antihistamines, decongestants, and expectorants) as suggested by Jaeger and further in view of the specific antihistamines and expectorant as suggested by Findlay and produce the instant invention. One of ordinary skill in the art would have been motivated to do this because the specific active substances taught by Findlay supplement the antitussive first drugs for ameliorating cough symptoms. All the references are useful for the same purpose (i.e. antitussive). It would have been obvious to combine equivalents that are known for the same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Therefore, the rejection of 07/08/11 is maintained.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 117-200 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 75-100, and 104-146 of copending Application No. 10/736,902 ('902 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '902 is promethazine and a pharmaceutically acceptable salt thereof. One with ordinary skill in the art would use various drugs that were compatible in the composition. Promethazine is an antihistamine and since an antihistamine can be a component of the instant dosage form (second drug of instant claim 121), one with ordinary skill in the art would be motivated to use it in the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 117-200 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-87 of copending Application No. 10/939,351 ('351 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '351 is phenylepherine and a pharmaceutically acceptable salt thereof. One with

ordinary skill in the art would use various drugs that were compatible in the composition. Phenylepherine is a decongestant and since a decongestant can be a component of the instant dosage form (second drug of instant claim 5), one with ordinary skill in the art would be motivated to use it in the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 117-200 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-20, 25, 27-39, 68-76, and 80-81, and 84 of copending Application No. 11/012,267 ('267 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '267 is diphenhydramine and a pharmaceutically acceptable salt thereof. One with ordinary skill in the art would use various drugs that were compatible in the composition. Diphenhydramine is an antihistamine and since an antihistamine can be a component of the instant dosage form (second drug of instant claim 5), one with ordinary skill in the art would be motivated to use it in the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 117-200 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48, and 56-62 of copending Application No. 11/115,293 ('293 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '293 is promethazine and a pharmaceutically acceptable salt thereof. One with ordinary skill in the art would use various drugs that were compatible in the composition. Promethazine is an antihistamine and since an antihistamine can be a component of the instant dosage form (second drug of instant claim 5), one with ordinary skill in the art would be motivated to use it in the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 117-200 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6-8, 12-13, 17-20, 21-24, 28-34, 38-41, 47-50, 60-65, 67-70, 73-74, 79-83, 86-90, 92, 95-96, 114, 117-119 of copending Application No. 11/115,321 ('321 hereinafter). Although the conflicting claims are not identical, they are not patentably distinct from each other because the first drug of the instant application is a morphine derivative, whereas the first drug of '321 is an antitussive that comprises a morphine derivative. Since a morphine derivative having antitussive activity is a component of the instant dosage

form (first drug of instant claim 1), one with ordinary skill in the art would be motivated to use it in the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

17. Applicant's arguments, see Page 28, filed 11/08/11, with respect to the provisional rejections on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims of copending application Nos. 10/736,902, 10/939,351, 11/012,267, 11/115,293 and 11/115,321 have been fully considered. Applicants request that these rejections be held in abeyance until the Examiner has indicated allowable subject matter. Applicants will then decide if the filing of one or more Terminal Disclaimers is warranted.

18. Applicants request is noted but until such time that allowable subject matter is identified, the provisional rejections on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims of copending application Nos. 10/736,902, 10/939,351, 11/012,267, 11/115,293 and 11/115,321 will be maintained. MPEP § 804 states that "The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications."

Conclusion

19. No claims are allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aradhana Sasan/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615